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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,900	06/23/2003	Charles S. Vann	9584-0049-999	2185

7590 06/15/2004

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EXAMINER	
LU, FRANK WEI MIN	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/602,900	VANN ET AL.	
	Examiner	Art Unit	
	Frank W Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 55 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 55 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 6/23/2003 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 1/2004.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: (1) since this applicant is a continuation of case 09/590,761, now US Patent No. 6,649,404, applicant is required to claim priority for this patent in the first sentence of the specification; (2) since case 09/227,799 has been abandoned, applicant is required to update the information for case 09/227,799 in the first sentence of the specification; and (3) there are Figures 35A, 35B, 35C, 36A, 36B, 36C, 37A, 37B, and 37C. However, the specification only describes Figures 35 to 37 (see the specification, page 12).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 55 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 55 is rejected as vague and indefinite. Since, in the first part of the claim, a chemical species has been immobilized on a fiber, it is unclear why the second part of the claim requires that said immobilized chemical species contacts said fiber and it appears that the second part of the claim means that said mobile chemical species contacts said fiber. Please clarify.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 55 is rejected under 35 U.S.C. 102(b) as being anticipated by Zolg (US Patent NO. 5,525,463, published on June 11, 1996).

Zolg teaches method and reagents for detection of mycobacteria using superoxide dismutase gene targeting.

Regarding claim 55, since Zolg teaches that alkali-denatured PCR mixtures obtained with the genus specific primers Z261 and Z212 from the 27 mycobacterial species (Table 1a) and 106 non-mycobacterial species (Table 2a) are diluted and spotted on prewetted solid supports (Gene Screen plus filters) using a 96-well manifold (see column 14, lines 15-46), the alkali-denatured PCR mixtures obtained with the genus specific primers Z261 and Z212 are immobilized chemical species as recited in the claim. Since Zolg teaches that the alkali-denatured PCR mixtures obtained with the genus specific primers Z261 and Z212 on the filters (Gene Screen plus filters) are crosslinked in a Stratagene UV-linker (see column 14, lines 15-46) and it is known that Gene Screen plus filter is a positively charged nylon membrane (see attachment), Zolg discloses immobilizing chemical species (ie., the alkali-denatured PCR mixtures) on a fiber (ie., a positively charged nylon membrane) as recited in the claim. Since Zolg teaches that hybridization is performed in a 50 ml Falcon tube using labeled genus specific probes (see column 14, lines 15-46), Zolg discloses disposing mobile chemical species (ie., labeled genus

specific probes) into said channel and placing said fiber on a support having a channel (ie., 50 ml Falcon tube) such that said immobilized chemical species contact said mobile chemical species as recited in the claim.

Therefore, Zolg teaches all limitations recited in claim 55.

Conclusion

7. No claim is allowed.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703)872-9306 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)272-0782.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
PSA
June 10, 2004

FRANK LU
PATENT EXAMINER

attachment C (part of the office action)

Southern Blotting

Preparation of Blotted Membrane

Note: this technique only works with **positively charged nylon** membrane eg. GeneScreen Plus.

1. Incubate gel in 0.25 N HCl for 10 minutes. The bromophenol blue should change color.
   - *the acid partially depurinates the DNA*
2. Incubate gel in 0.4 N NaOH for 30 minutes. The bromophenol blue color should change back.
   - *the hydroxide breaks the phosphodiester backbone at depurinated sites, fragmenting large pieces of DNA to sizes suitable for transfer*
3. Cut membrane to exact size of gel. Also cut 6 pieces of Whatman filter paper to the size of the gel, plus one piece as wide as the gel, but longer.
4. Pre-wet the membrane in 0.4 N NaOH for approximately 10 minutes.
5. Fill a tray with 0.4 N NaOH, place a piece of glass on the tray.
6. Soak the large piece of Whatman paper in the NaOH, place on the glass so that each end hangs down into the NaOH solution, and remove bubbles by rolling with a pasteur pipette.
7. Place the gel on the paper on the glass, again remove bubbles.
8. Place the pre-wet membrane on the gel, again removing any bubbles.
9. Place 3 pieces of Whatman paper pre-wet with NaOH one-at-a-time on the membrane, removing bubbles and wrinkles for each piece.
10. Place 3 dry pieces of Whatman paper one-at-a-time on the wet papers, removing bubbles and wrinkles for each piece.
11. Place a stack of paper towels on the dry Whatman papers, and apply a small weight.
12. Allow to blot overnight.
    - *literature suggests 2 hours is sufficient. not sure that this is actually the case*
13. Remove the paper towels and filter paper. Mark the wells of the gel on the membrane with pencil.
14. Rinse the membrane in 0.2 M Tris pH 7.5 - 2x SSC and allow to dry completely.
    - *on filter paper works well*

Hybridization of DNA

1. Prehybridize the membrane in hybridization solution for at least 30 minutes at 65C.
   - *one effective method is to prehyb with the DNA side of the membrane facing into the solution for 10 mintutes, then reverse the membrane orientation to prehybridize with the non-DNA side of the membrane facing into the solution for 10 minutes, then finally reverse orientation again and prehybridize with the DNA side of the membrane facing into the solution for at least an additional 30 minutes.*
     - *do all of these prehybridization steps at 65C*
     - *the goal is to block non-specific binding sites on the membrane efficiently on both sides of the membrane*
2. Label your probe while the membrane is prehybridizing. Use 10 - 15 ng probe per membrane.
   - *more is **not** better*
3. Pour off the hybridization solution and add fresh, prewarmed solution.
4. Add the probe and hybridize at 65C overnight.
5. Pour off the hybridization solution into the radioactive waste.